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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/077,572	10/13/98	APICELLA M	875001US2

HM12/0301
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EXAMINER

DEVI, S

ART UNIT PAPER NUMBER

1641

DATE MAILED: 03/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/077,572Applicant(s)
Apicella et al.Examiner
S. Devi, Ph.D.Group Art Unit
1641☒ Responsive to communication(s) filed on Oct 13, 1998☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 1-29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☐ Claim(s) _____ is/are rejected.☐ Claim(s) _____ is/are objected to.☒ Claims 1-29 are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

- 1) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 2) Restriction to one of the following inventions is required under PCT Rule 13.1 and 13.2:
- I. Claims 1-21, 27 and 28, drawn to a vaccine formulation comprising an *htrB* mutant of a gram-negative bacterial pathogen, a method of making the mutant and a method of immunizing using the vaccine, classified in class 424, subclasses 93.4 and 184.1
 - II. Claims 22-26 and 29, drawn to a mutant endotoxin of reduced toxicity, a method of making the mutant endotoxin and a method of producing endotoxin-specific antisera, classified in class 536, subclass 123.1 and class 435, subclass 101.
- 3) The special technical feature of invention I is a whole cell mutant bacterium, a method of making the mutant and a method of using the mutant as a vaccine. The special technical feature of invention II is a mutant endotoxin, a method of making it and a method of using it for producing specific antisera. Individually, these are permitted combinations of categories under PCT Rule 13.2. Inventions I and II are clearly drawn to two distinct products: a whole cell bacterium and an endotoxic component of a bacterium, each with specific and independent utility. Both products can have independent therapeutic and non-therapeutic, prophylactic and non-prophylactic, and diagnostic utilities in *in vitro* assays for example. As therapeutic or prophylactic components, these products can elicit distinct biologic and immunologic effects. The special

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technical features of the two inventions are not so linked because the endotoxin of invention II can be synthesized independently without the use of the bacterium of invention I, for example, by a chemical synthetic process. The bacterium of invention I and the endotoxin of invention II can be used for a materially different process of using the products such as, in an *in vitro* diagnostic assay as sources of coating antigens.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

- 4) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 5) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).
- 6) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 am to 4.15 pm. A message may be left on Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

February 1999


JAMES C. HOUSEL 2/26/99
SUPERVISORY PATENT EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER: Dr. S. Devi

ART UNIT: 1641

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: _____

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

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